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## United States Senate

COMMITTEE ON  
GOVERNMENTAL AFFAIRS  
WASHINGTON, D.C. 20510

RICHARD A. WIGMAN  
CHIEF COUNSEL AND STAFF DIRECTOR

January 3, 1978

The Honorable Elmer Staats  
Comptroller General of the  
United States  
Washington, D. C. 20548

Dear Mr. Staats:

As you are aware, the Governmental Affairs and Human Resources Committees have active and long-standing interests in the performance of the Food and Drug Administration's vaccine regulatory policies. As you may recall, in 1972, a Governmental Affairs Subcommittee on Executive Reorganization and Government Research conducted an extensive investigation of the Food and Drug Administration. A major focus of that investigation concerned Federal involvement in vaccine regulation, and specifically, the performance of the Division of Biologic Standards (DBS) at the National Institutes of Health. As part of this investigation, the General Accounting Office conducted a study entitled "Problems Involving Effectiveness of Vaccines." As a result of these efforts, the role of the Federal Government in the regulation of vaccines was substantially changed, and the DBS was transferred to the Food and Drug Administration as the Bureau of Biologics (DOB). Over the past several years, the Human Resources Subcommittee on Health and Scientific Research has held extensive hearings on vaccine policy.

Both Committees are aware of the increasing evidence that there are still significant problems in the Federal Government's regulation of biologics. The swine flu program, whatever its merits, resulted in a substantial loss in public confidence in the Federal Government's assurances as to the safety and effectiveness of vaccines in general. It would be a tragedy if this lack of confidence translated into reluctance on the part of the public to take the many vaccines which have been clearly proven to be safe, effective and essential, such as measles, polio, rubella, mumps, tetanus, diphtheria, and whooping cough.

The Federal Government's swine flu program raised many important questions relating to the Federal Government's efforts to ensure that the public is immunized against serious health threats. Your recent report dated June 27, 1977, entitled "The Swine Flu Program: An Unprecedented Venture in Preventive

"Medicine" is an important first step in pointing out strengths and weaknesses of our Federal response to this perceived threat. As such, it is an important first step in restoring public confidence in the Federal public health establishment. However, we believe more work needs to be done.

It has been several years since the Bureau of Biologics began regulating vaccines from within the Food and Drug Administration. In recent months, serious questions have again been raised about the effectiveness of BOB; therefore, on behalf of both the Governmental Affairs and Human Resources Committees, we request that the General Accounting Office undertake a study of the activities of the Bureau of Biologics, specifically answering the following questions:

A. How useful and effective is the Bureau's adverse reaction reporting system? To what degree are adverse reactions noted by physicians, public health officers and biologics manufacturers' personnel reported to the BOB, and does the system ensure that reported adverse reaction information is channeled to those who would be helped by receipt of this information?

B. How effective is the Bureau's program to regulate the informational content of labels of biologics in general and vaccines in particular?

C. How effective has the Bureau regulated allergenics to ensure efficacy as well as safety, potency and purity?

D. How reliable are the Bureau's biological test methods such as the CCA test for influenza vaccine, the neurovirulence test for polio, measles, and other vaccines and tests to detect viral contaminants in vaccines prepared in chicken eggs, chicken cell and other animal cultures, and in artificial media?

E. How effectively does the Bureau examine vaccines and other biologics for trace metals and other extraneous materials and what are the medical consequences of the presence of trace metals in biologics?

F. How effective is the Bureau's management in the following areas:

1. In maintenance and morale of individual staff members?

2. In maintenance of clear lines of authority in its decision-making activities?

3. In its ability to provide for, ensure, and take cognizance of dissenting opinions generated within and without the Bureau; and

4. In the general administration of its responsibility to ensure safe, potent, pure and effective biologics?

G. How is the Bureau now applying what was learned from the swine flu vaccination program in the measles immunization area?

H. What is the relationship between the research and control functions of the Bureau, and are most or any of its research activities more appropriate for conduct under the auspices of the National Institutes of Health?

I. Is there an adequate and timely supply of vaccines available for use in the United States? What are the obstacles to continued availability? How many firms are involved in the manufacture of vaccines? Which vaccines are produced by only one or two companies? Is the continued availability of these vaccines assured or does it depend on certain conditions? What are they?

J. What is the current state of the liability controversy with vaccines? How is liability handled today? What is the potential for liability questions threatening the continued availability of vaccines?

K. Is adequate informed consent obtained when vaccines are administered? When two forms of vaccine are available, as with the polio vaccine (live or killed), how is informed consent handled? What impact does this have on a company's liability?

In addition, we request that the General Accounting Office look at the relationship between the Center for Disease Control, the National Institutes of Health, and the Food and Drug Administration with respect to their individual roles in setting national vaccine policy. How well are they coordinating their efforts?

Finally, we would like the General Accounting Office to investigate the professional relationships between those professionals working in any capacity to assist DOB in setting various vaccine policies and the major pharmaceutical manufacturers. To what extent do such relationships raise the possibility of real or apparent conflicts of interest?

The Honorable Elmer Staats

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We are looking forward to a productive investigation.  
Thank you for your cooperation.

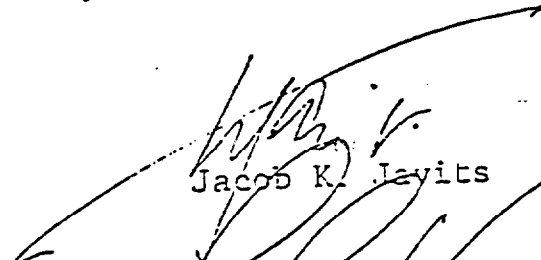
With best wishes,

Sincerely,

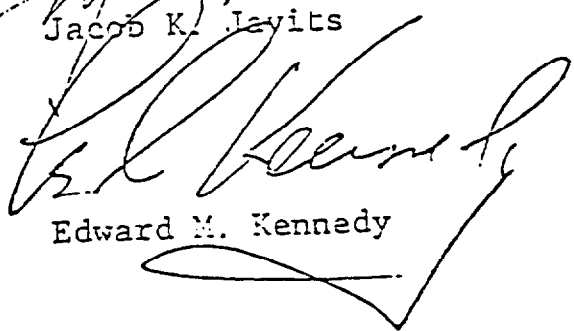


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